

Metabolic and cardiovascular response to common food and drink ingredients

Submission date 04/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/10/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims:

Obesity (being extremely overweight) is a major health problem all over the world. People who are obese are at high risk of developing a number of serious health problems including heart disease, type 2 diabetes, cancer and osteoarthritis. One way to prevent and treat obesity is to increase the amount of energy we burn (called our energy expenditure). Exercise programs can be difficult and/or inconvenient, and special diets can be difficult to stick with for a long period of time. Some common food and drink ingredients have the potential to increase energy expenditure, for example caffeine. It has been suggested that certain other foods and drinks, such as cold water, also increase the amount of energy we burn, but these cases have not yet been accurately tested. Here, we have designed a study to investigate different common food and drink ingredients that may influence our metabolic rate, by precisely determining their effect on energy expenditure and what happens when we change their amount, type and temperature.

Who can participate?

Healthy men and women aged between 20-40 years.

What does the study involve?

The energy expenditure (amount of energy burned) is measured before and after each participant takes in a drink or meal containing one of 4 common food and drink ingredients. These are:

1. Protein. We are looking at the effect of protein on energy expenditure and what happens if we change the amount of protein in a meal.
2. Sugar. We are looking at the effect of sugar on energy expenditure and what happens if we change the type of sugar in a meal.
3. Methylxanthines. These are stimulants found in the diet, like caffeine (found in tea, coffee, and energy drinks) and theobromine (found in chocolate). How do these affect energy expenditure?
4. Mineral water. We are looking at how the temperature of the water may affect energy expenditure.

All participants can be given all meals/drinks tested in the study, or just a number of them, but the order in which they are given each meal/drink are randomly allocated. Energy expenditure is

assessed by measuring the amount of O₂ and CO₂ in the air that each participant breathes out. The effect of each of these meals/drinks on the heart are also measured with small electrodes stuck to their chest (this process is non-invasive and painless). These measurements are made while the participants have fasted (having not eaten anything for 12 hours before the test), and after they have consumed the test meal/drink. Each participant is interviewed about their lifestyle with regard to diet and physical activity, and their body composition (height, weight, fat mass and muscle mass) is measured. In order to measure their normal, daily physical activity and body temperature, each participant is given a wireless monitor which straps to their chest to wear continuously for one week.

What are the possible benefits and risks of participating?

There will be no direct benefit to the participants taking part in the study. However, the study will enable us to answer some questions about how the body responds to the different food and drink ingredients and what factors might determine how an individual will respond. In most healthy persons there should be no disadvantage in taking part in this study. However, possible side effects include a small headache and/or increase in heart rate following consumption of some of the food ingredients we are testing (for example, caffeine or cold water).

Where is the study run?

Department of Medicine, University of Fribourg (Switzerland)

When is the study starting and how long is it expected to run for?

January 2013 to January 2018

Who is funding the study?

Department of Medicine, University of Fribourg (Switzerland)

Who is the main contact?

Professor Abdul Dulloo

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Contact information

Type(s)

Scientific

Contact name

Prof Abdul Dulloo

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Measuring the acute thermogenic cardiovascular effects of common food and drink ingredients (dietary protein, sugars, methylxanthines & water)

Study objectives

The main aim of this study is to determine the thermogenic properties of several common food ingredients (dietary protein, sugars, methylxanthines and water), and how individuals differ in terms of their metabolic and cardiovascular responses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single centre randomized interventional study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Diet-induced thermogenesis

Interventions

Interventions

1. Protein: A standardised test meal containing 10 to 40 %kcal protein
2. Sugar: A standardised test drink containing sucrose, glucose, fructose, lactose or galactose

dissolved in distilled water

3: Methylxanthines: A standardised test drink containing coffee, chocolate, tea or energy drink (Red Bull), or equivalent amount of methylxanthines (caffeine, theobromine)

4: Bottled Water: Commercial bottled mineral water, or the equivalent quantity of bicarbonate dissolved in distilled water

Control

An equal volume of distilled water served at room temperature

All studies will be conducted with drinks at either room temperature or 3°C, and at rest or during standardized low-intensity activities (described in ISRCTN82088414).

Each participant will complete all interventions for the protocol in which they are enrolled (i.e., protein, sugar, methylxanthine or water) in addition to the control intervention. The order of the interventions within each protocol will be randomized.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Energy expenditure will be measured by indirect calorimetry before and after the ingestion of each food/drink ingredient

Secondary outcome measures

1. Cardiovascular response (heart rate and blood pressure) will be measured by continuous physiological monitoring before, during and after each intervention
2. Body composition will be measured at the start the study
3. Dietary and lifestyle information will be collected by questionnaire
4. Body temperature and habitual physical activity will be measured by wireless physiological monitoring over a period of one week

Overall study start date

01/01/2013

Completion date

01/01/2018

Eligibility

Key inclusion criteria

1. 20-40 years old
2. Healthy as determined by medical history
3. Signed consent given

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Pregnancy
2. History of eating disorders
3. History of metabolic diseases (e.g. diabetes)
4. History of cardiovascular disease
5. History of neurological or psychiatric disorders
6. History of gastro-intestinal disorders
7. Any other condition that might impair the subjects ability to participate in the study

Date of first enrolment

01/01/2013

Date of final enrolment

01/01/2018

Locations

Countries of recruitment

Switzerland

Study participating centre

Department of Medicine (Physiology)

Fribourg

Switzerland

1700

Sponsor information

Organisation

University of Fribourg (Switzerland)

Sponsor details

c/o Professor Jean-Pierre Montani

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Sponsor type
University/education

Website
<http://www.unifr.ch/>

ROR
<https://ror.org/022fs9h90>

Funder(s)

Funder type
University/education

Funder Name
Department of Medicine, University of Fribourg (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration